

## REMARKS

### **I. RESTRICTION REQUIREMENT**

#### **Restriction of Inventions**

The Office Action states that the present claims comprise 5 independent inventions as follows:

Group	Claims	Drawn to:
1	1, 2, 4, 10-14, 16, 18-20, 22-23	a method for obtaining a prognosis for a subject having or at risk of developing an inflammatory condition.
2	32-34,	a method for selecting a group of subjects for determining the efficacy of a candidate drug known or suspected of being useful for the treatment of an inflammatory condition.
3	36, 44-50, 53, 56, 58, 60-62, 64-68	a method of treating an inflammatory condition in a subject in need thereof. <b>(elect)</b>
4	69, 73, 75, 79, 83, 85, 86, 87	oligonucleotides and compositions comprising oligonucleotides.
5	84	a computer readable medium

The Action alleges that the restriction is being made because, under PCT Rules, the groups do not relate to a single general inventive concept, and therefore lack the same or a corresponding special technical feature that would define a contribution over the prior. The basis for this position is the conclusion that the technical feature linking the Groups is “polymorphic sites in the Protein C gene.” The Office based its position on Spek *et al.* (*J. Biol. Chem.* 270:24216-21). Spek allegedly teaches

- (1) two mutations in the promoter region of the human protein C gene causing thrombosis (abstract)
- (2) oligonucleotides specific for the detecting polymorphisms (pg. 24217).

Thus, there is no special technical feature linking the recited groups, as would be necessary to fulfill the requirement for unity of invention.

#### **ELECTION OF SPECIES**

The Office Action includes five separate determinations that multiple species of a single generic invention are present. Only four of those are discussed below and are limited to discussion of claims of Group 3 (the Group that Applicants are electing below).

A. First Determination of Species

- the Protein C sequence (SEQ ID NO:1),
- the EPCR sequence (SEQ ID NO:2), and
- both the Protein C and EPCR sequences (SEQ ID NOs:1 and 2).

The Action indicates the following Group 3 claims to be generic to the above species:

**Claims 36, 44-50, 53, 58, 60-62, 64-68**

The reason these species are deemed not to relate to a single general inventive concept under PCT Rules is because

...the different genes encompassed by the claims fail to share a common property or activity because each gene consists of a unique nucleotide sequence, has a distinct melting temperature, and a distinct specificity of hybridization. Further each gene encodes for a protein having a distinct amino acid sequence and a distinct biological activity. Additionally the genes fail to share a common structure with one another.

B. Second Determination of Species

- each SNP, and
- each combination of SNPs

encompassed by the claims. The Action notes that election must be commensurate with the species election in A above.

The Action indicates the following Group 3 claims to be generic to the above species:

**Claims 36, 44-50, 53, 56, 58, 60-62, 64-68**

The reason these species are deemed not to relate to a single general inventive concept under PCT Rules is because

...the description fails to disclose that all of the SNPs share a common property or activity. Further the SNPs do not share the same structure

C. Third Determination of Species

- each inflammatory disease encompassed by the claims.

Applicant is required to elect a single inflammatory disease. The Action indicates the following Group 3 claims to be generic to the above species:

**Claims 36, 44-48, 50, 53, 56, 58, 60-62, 64-68**

The reason these species are deemed not to relate to a single general inventive concept under PCT Rules is because

...the description fails to disclose that each of the diseases shares common property or activity. Further each disease does not share the same structure.

*(Applicants believe the latter statement of "diseases not sharing structure" was the unintentional 'dominance' of boilerplate usage over careful attention to the invention being described.)*

**D. Fourth Determination of Species**

- each anti inflammatory agent and anti-coagulant agent encompassed by the claims.

Applicant is required to elect a single species (a single anti inflammatory agent or a single anti coagulant agent. The Action indicates the following Group 3 claims to be generic to the above species:

**Claims 36, 44-48, 50, 53, 56, 58, 60-62, 64-66**

The reason these species are deemed not to relate to a single general inventive concept under PCT Rules is because

...the description fails to disclose that each of the anti inflammatory agents and each of the anticoagulant agents shares common property or activity. Further each of these agents do not share a common structure.

**II. APPLICANTS' RESPONSE**

**Election of Invention]**

Applicants traverse the Office's Restriction above on the basis that the it would not burdensome to examine all the indicated groups together under MPEP 806.05(c).

To advance prosecution, however, Applicants elect, Group 3 (method claims 36, 44-50, 53, 56, 58, 60-62, 64-68) and withdraw from consideration the claims that constitute Groups 1, 2, 4 and 5.

**Election of Species**

Applicants elect the following species for initial examination (referencing the section of the species election requirements indicated above:

- the Protein C sequence (SEQ ID NO:1)**
- the SNP at position 4732 of the Protein C sequence (SEQ ID NO:1)**
- “systemic inflammatory response syndrome” (SIRS) as the inflammatory disease.**
- activated protein C as an anti-inflammatory agent.**

Claims 36, 44-48, 50, 53, 56, 58, 60-62, 64-68 are generic to species A-C, whereas all of these but claim 68 are generic to species D.

**III. 2<sup>nd</sup> PRELIMINARY AMENDMENT**

Only claim 48 is amended voluntarily for greater clarity. This amendment does not introduce new matter and its entry is respectfully requested.

As a result of the foregoing elections and amendments, the status of the claims is as follows:

Pending claims: 1, 2, 4, 10-14, 16, 18-20, 22, 23, 32-34, 36, 44, 50, 53, 56, 58, 60-69, 73, 75, 79 and 83-87.

Active claims: 36, 44-50, 53, 56, 58, 60-62, 64-68.

Withdrawn claims: 1, 2, 4, 10-14, 16, 18-20, 22-23, 32-34, 69, 73, 75, 79, 83-87.

**IV. CONCLUSION**

Applicants respectfully request entry of the foregoing claims as amended, Applicants' elections and Applicants' request for reconsideration of the restriction requirement as discussed. The application is now in condition for Examination on the merits and allowance.

Respectfully submitted,

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